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Ensuring Safe MRI Examinations and Earlier Detection of Recurrent Cancer: A Scoping Review to Identify Breast Tissue Expanders That are Safe for High-Risk Breast Cancer Survivors

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Abstract

Purpose

This capstone project aims to conduct a scoping review to identify breast tissue expanders that are safe for high-risk breast cancer survivors, ensuring safe magnetic resonance (MR) examinations. The goal is safe MR examinations for early detection of recurrent cancer, post-operative evaluation, monitoring, and reducing preventable morbidity and mortality.

Background

The MR safety of manufacturers' tissue expanders is defined according to the United States Food and Drug Administration (FDA) guidelines and regulations as MR Conditional or MR Unsafe. Before 2023, there was a safety concern about using tissue expanders containing a magnetic port during the first stage of breast reconstructive surgery, as these were categorized as MR Unsafe for breast cancer survivors (Clausen-Oreamuno, 2024; Dibbs et al., 2019). FDA magnetic resonance imaging (MRI) medical device guidelines state that MR Unsafe devices pose unacceptable medical risks for patients having an MR examination, creating barriers for cancer survivors needing safe MR examinations (FDA, 2023b). Consulting with MR safety experts provided a deeper understanding of ensuring safe MR examinations and potential concerns related to surgically implanted medical devices.

Methods

The scoping review involved a comprehensive literature search on Medline, Science & Technology Collection, Google Scholar, and Cochrane. This search aimed to gather data from research studies to conduct a scoping review to identify breast tissue expanders that are safe for high-risk breast cancer survivors, ensuring safe MR examinations, earlier detection of recurrent cancer, post-operative evaluation, monitoring, and reducing preventable morbidity and mortality.

Results

The search initially yielded 52 articles, of which 11 were selected for inclusion in this scoping review. Articles unrelated to tissue expander and MRI compatibility were excluded. Additional resources included consulting with MRI experts and stakeholders, reviewing the FDA 510(k) clearance process, FDA guidelines, imaging and plastic surgery standards, and MR safety regulations.

Conclusion/Implications

This scoping review applies the Health Belief Model to explain the factors that influenced the adoption of the first MR Conditional tissue expander in the United States in 2023. The scoping review highlights the controversy surrounding MR examinations for patients with breast tissue expanders containing magnetic ports. The scoping review and stakeholder consultations provided further insight into the necessary steps for a medical device to progress through the FDA 510(k) clearance for surgical use and emphasized the importance of MR safety guidelines and medical device safety guidelines. Implementing the new MR Conditional tissue expander in 2023 aims to ensure safer MR examinations and earlier detection of recurrent cancer in cancer in high-risk patients, ultimately reducing preventable morbidity and mortality.

Chapter 1: Introduction

In 2023, nearly 255,000 people in the United States were newly diagnosed with breast cancer, many of whom could benefit from breast reconstruction to improve their quality of life (Siegel et al., 2023; Clausen-Oreamuno, 2024). Patients can choose reconstructive surgery following a complete or partial mastectomy due to cancer, surgery after trauma, or due to underdeveloped breasts to replace tissue that has been removed or failed to develop (FDA, General and Plastic Surgery Devices Panel, 2022a; 2022b; 2023c). During the initial breast

reconstruction surgery, tissue expanders with magnetic or non-magnetic ports are temporarily placed subcutaneously or submuscular to develop the coverage of additional tissue or surgical flaps (FDA, General, and Plastic Surgery Devices Panel, 2022a; 2022b; 2023c). The small magnetic port allows the medical practitioner to accurately locate the port for the saline injections at the post-operative appointments.

If the tissue expander contains a magnetic port, this surgical device is categorized as MR Unsafe according to the tissue expander medical device guidelines and the FDA regulations for medical device safety in an MR environment. The FDA safety and compatibility guidelines for medical devices in MR environments significantly limit access to MR imaging for post-cancer patients until the tissue expanders with a magnetic port are surgically removed (FDA, 2023h). MRI is the best radiological modality for early detection of recurrent cancer in high-risk patients (Clausen-Oreamuno, 2024). These barriers to MR examinations impede post-operative evaluation, monitoring, and early detection of recurrent cancer for high-risk patients (Clausen-Oreamuno, 2024; FDA, General, and Plastic Surgery Devices Panel, 2022a; 2022b; 2023c).

This scoping review reflects controversial conclusions on MR safety guidelines with medical devices for patients with tissue expanders containing a magnetic port. Before 2023, the FDA guidelines for “labeling medical devices for safety in the MR environments” and medical device manufacturers labeled all breast tissue expanders as MR Unsafe (FDA, 2023h). Per the FDA, for safe MR examinations, one “can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations” (FDA, 2023h). There are different approaches to MR examinations with various settings, but misinformation regarding safe MR examinations leads to cancer survivors facing barriers to accessing MR imaging. In 2023, the

FDA granted 510(k) clearance for the first tissue expander with an MR Conditional non-magnetic port, marking a transformative step in breast cancer reconstruction. Consulting with MRI experts on MR safety provided insights into MRI expertise, leading to a deeper understanding (Dibbs et al., 2019).

Research question

This scoping review addresses the question, "What are the necessary steps to identify breast tissue expanders that are safe for high-risk breast cancer survivors and ensure safe MR examinations?" The framework of a research question applies the population, intervention, comparison, outcome, and context (PICOC) method.

Population

Individuals who have undergone a mastectomy in the past twelve months due to breast cancer and require at least one tissue expander in the first stage of breast reconstruction surgery.

Intervention

Identify breast tissue expanders that are safe for high-risk breast cancer survivors, ensuring safe MR examinations, allowing earlier detection of recurrent cancer, post-operative evaluations, monitoring, and reducing preventable cancer morbidity and mortality.

Comparison

This study compares the two different FDA MR safety labels, MR Conditional and MR Unsafe, for breast tissue expander medical devices. Data was gathered from research studies on safe MR examinations, and MR safety specialists were interviewed to gather additional MR safety data.

Outcome

The outcome identifies breast tissue expanders as safe for high-risk breast cancer

survivors and ensures safe MR examinations amongst two different FDA MR safety labels for medical devices: MR Conditional and MR Unsafe. This outcome includes FDA regulatory considerations, literature reviews, identifying concerns about safe MR examinations, and consulting with MRI experts and stakeholders.

Context

Context refers to high-risk breast cancer survivors who had a mastectomy. The context frames the research question and guides the scoping process to gather data from research studies, interviews related to plastic reconstructive surgery, breast cancer, surgical medical devices, breast tissue expanders, safe MR examinations, MR screening, expert MRI specialists on safe MR examination, mammography, early detection of recurrent breast cancer, MR Conditional breast tissue expanders with a non-magnetic port, health disparities, coronavirus disease 2019 (COVID-19), global MRI experts, FDA guidelines, regulations, classifications and medical device advisory.

Objectives/Aims

This scoping review aims to:

- Identify a breast tissue expander in the first stage of breast reconstructive surgery that is safe for high-risk breast cancer survivors, ensuring safe MR examinations and early detection of recurrent cancer.
- Identify benefits, risks, safety, and efficacy for high-risk breast cancer survivors with MR Unsafe breast tissue expanders with magnetic ports versus MR Conditional breast tissue expanders with a non-magnetic port.
- Identify misinformation related to MR Unsafe tissue expanders with magnetic ports.
- Analyze recommendations from regulatory bodies, including FDA safety guidelines and

requirements, and expert insight into MR safety.

- Identify organizations and agencies required or related to the innovation and implementation of an MR Conditional tissue expander that will be accessible for surgical use in the United States in 2023.
- To define gaps in implementing a new medical device accessible in hospitals and collaborate with public health stakeholders to promote MR Conditional breast tissue expanders that are safe for MR examinations.

Rationale for the Review

- To improve early detection of recurrent breast cancer in high-risk cancer patients.
- To reduce preventable recurrent breast cancer morbidity and mortality.
- To promote safer breast reconstruction practices and safe MRI access for high-risk breast cancer patients.

The study aims to complete a scoping review to identify breast tissue expanders in the United States labeled MR Conditional or MR Unsafe for patient MR examinations after the first stage of breast reconstruction surgery and to determine whether other radiological modality options exist.

Chapter 2: Background and Literature Review

Significance

This scoping review aims to identify breast tissue expanders that are safe for high-risk breast cancer survivors and ensure safe MR examinations for early detection of recurrent cancer. Before October 2023, all breast tissue expanders in the United States used in the initial breast reconstruction surgery contained a magnetic port, resulting in limitations due to their MR Unsafe labeling with FDA regulations (Clausen-Oreamuno, 2024; FDA, General and Plastic Surgery

Devices Panel, 2022a; 2022b; 2023c). The absence of FDA-labeled MR Conditional tissue expanders accessible in the United States until 2023 delayed early detection of recurrent cancer until the MR Unsafe tissue expanders were surgically removed, per FDA guidelines (Clausen-Oreamuno, 2024; FDA, General and Plastic Surgery Devices Panel, 2022a; 2022b; 2023c). Established MR procedural guidelines advise trained MR radiologists on MRI settings and provide specific patient MR examination protocols. These established guidelines can be followed when the benefits of MR imaging outweigh the risks for patients with an FDA-labeled MR Unsafe breast tissue expander with a magnetic port (Dibbs et al., 2019). Early cancer detection with MR imaging is crucial for high-risk recurrent cancer patients, and MR Conditional tissue expanders address these needs by ensuring safe MR examinations.

Literature Review

Health Belief Model

I reviewed studies on the Health Belief Model in the context of breast tissue expanders labeled MR Unsafe with a magnetic port and early detection of recurrent cancer. Additionally, I reviewed research focusing on breast tissue expanders labeled MR Conditional with a non-magnetic port, their adoption, and their association with early detection of recurrent cancer, ensuring safe MR examinations.

Patient and Provider Perceptions

I further explored existing research on patients' and providers' perceptions of the impact of breast tissue expanders with a magnetic and non-magnetic port.

Impact of Innovation

I assessed the impact of innovations with breast tissue expanders with a non-magnetic port labeled MR Conditional for MR examinations and the steps required to implement these

advancements into surgical practice for post-cancer patients.

Background

When post-cancer patients have a complete or partial mastectomy, the initial breast reconstruction surgery will include a tissue expander surgically implanted. This context is multifaceted, innovating the first breast tissue expander with a non-magnetic port labeled as MR Conditional, which was available in the United States for post-cancer patients in 2023. There are many entities I reviewed to grasp the background of the high acuity of breast cancer and breast reconstruction use of tissue expanders that are labeled MR Unsafe with a magnetic port.

Breast cancer mortality for women in the United States is reduced with screening for early detection, early diagnosis, and treatment (World Health Organization [WHO], 2022). Per the *International Classification of Diseases for Oncology* (2017-2019), breast cancer is the second leading cause of mortality in the United States, and one in eight women in their lifetime will develop breast cancer (Siegel et al., 2023). Inequalities exist in breast cancer rates, with high Human Development Index (HDI) countries showing one in twelve women will be diagnosed with breast cancer in their lifetime and a breast cancer mortality rate of one in seventy-one women (WHO, 2024). In low HDI countries, the rates are one in twenty-seven women will be diagnosed with breast cancer in their lifetime, and a breast cancer mortality rate of one in forty-eight women (WHO, 2024). In the United States, the incidence of breast cancer in 2023 is rising, and it is the second leading cause of mortality worldwide. Breast cancer is the most common newly diagnosed cancer in 2020 and the fifth leading cause of cancer-related deaths worldwide in 2020, but early detection can likely respond to treatment (Siegel et al., 2023; WHO, 2022).

Dahan et al. (2021) found that MR examinations are the best imaging method for

estimating the tumor size for breast cancer. A systematic review article revealed that the average duration for a breast cancer tumor to double in size is 180 days, highlighting the need for safe MR examinations, with MR screening the gold standard for early detection of recurrent cancer for high-risk patients (Dahan et al., 2021). An example of doubling time is HER2 positive breast cancer doubling time, which is 160 ± 60 days per Ryu et al. (2014) compared to 184 ± 71 days per Zhang et al. (2017). According to the American Cancer Society (2024), MR screening and a mammogram are recommended for high-risk patients. With the average doubling time in breast cancer tumor growth of 180 days, this underscores the critical need to safely access MRI for earlier detection of recurrent cancer in high-risk patients (Dahan et al., 2021).

The screening, diagnosis, treatment, and follow-up care for breast cancer patients have directly been impacted by Coronavirus disease 2019 (COVID-19) (Uscher et al., 2023). Breast reconstruction within the first few months of COVID-19 was impacted, with many hospitals halting breast reconstructive procedures when the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) recommended delaying elective surgeries to avoid COVID-19 exposure and increase the focus on the care for COVID-19 patients (Uscher et al., 2023). Commonly, when breast cancer is surgically removed as a partial or complete mastectomy, those electing breast reconstruction have breast tissue expanders surgically placed during this initial surgery. During the COVID-19 pandemic, there were delays in breast cancer care and postponed procedures for autologous reconstruction. During COVID-19, breast cancer patient's medical appointments were spread out, and post-surgery hospital stays were shortened (Uscher et al., 2023).

Breast reconstruction was halted except for those patients with more aggressive cancer, such as HER2-positive or triple-negative breast cancer, with the precedence of hospital care for

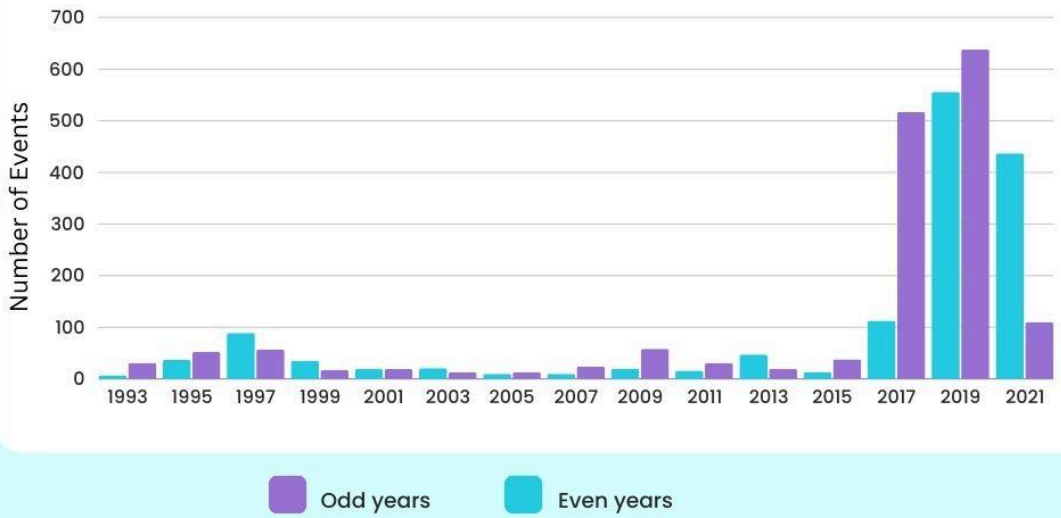
COVID-19 patients (Uscher et al., 2023). Newly diagnosed cancer patients waited months for surgical procedures, compared to an average duration of just a few weeks for the initial breast reconstructive surgery prior to COVID-19 (Uscher et al., 2023). In 2020, to reduce the length of inpatient hospital recovery, 76.3% of breast reconstruction surgeries involving tissue expander placement were reclassified as outpatient procedures, though delays in tissue expander surgical procedures persisted (Pires et al., 2023). Secondary risks following tissue expander placement include infection, prolonged tissue expander implantation complications, and delayed or missed cancer diagnosis (FDA, General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, 2023c).

According to the FDA classification of medical devices, Title 21 of the Code of Federal Regulations (CFR) Part 860.7, Subsection (d) Paragraph (1) acknowledges that a device is safe and there are probably health benefits from the intended use of the device, and if any risks, the benefits outweigh the risks based on evidence (FDA, General and Plastic Surgery Devices Panel, 2022b). The "General and Plastic Surgery Devices Advisory Panel of the Medical Devices Advisory Committee" is led by the FDA and met in October 2022 to discuss the classification of tissue expanders, discuss potential risks, and review individual medical device reports (MDRs) (FDA, General and Plastic Surgery Devices Panel 2023c, p. 4). No specific discussion related to safe MR examinations or safety concerns related to individual MDRs documented was noted in these FDA advisory notes accessible to review (FDA, General and Plastic Surgery Devices Panel 2023c). Tissue expanders with magnetic port information packets state that diagnostic testing with MRIs is contraindicated in patients with tissue expanders in place (Allergan, 2018). In evidence-based articles, there is a variety of MRI access and safety responses from medical professionals regarding patients with tissue expanders and MR examinations.

Since 1993, the FDA has reported 5,573 Medical Device Reports (MDRs) of serious injuries (see Figure 1) secondary to tissue expanders, with an increase in the number of MDRs reported annually from 2018 to 2021 that was due to a recall of a specific tissue expander with an increased risk for "Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)" (FDA, General and Plastic Surgery Devices Panel, 2022b, slide 9). The FDA gathers MDRs on reported adverse events, and based on these literature reviews; the FDA has identified the following health risks secondary to tissue expanders: skin trauma possibly leading to necrosis, reoperation due to device failure or malfunction, infection, adverse tissue reaction, pain and breast implant illness (BHI) related to the tissue expander being present in the breast, the third highest risk is BIA-ALCL (FDA, General and Plastic Surgery Devices Panel, 2022a; 2022b).

Figure 1

Number of MDRs received for tissue expanders since 1993



Note. From 1993-April 1, 2022 there were 5,573 serious injury MDRs received from the Alternate Summary Reporting (ASR) Program. The top three causes of MDRs received for tissue expanders, 2,358 causes of MDRs were unknown, 769 causes of MDRs were due to implant failure, 739 causes of MDRs were due to surgical procedure. Adapted from "FDA Executive Summary," by FDA, 2023c, p. 55 https://www.fda.gov/media/162541/download

The FDA bases guidance for MR labeling of all medical devices consistent with the

American Society of Testing and Materials (ASTM International) F2503 “Standard practice for marking medical devices and other items for safety in the MR environment” (FDA, 2023h). The FDA has rigid MR safety guidelines for medical devices in an MR environment, regulations for medical device labeling, mandatory medical device reporting guidelines, and a general and plastic surgery device panel of the medical devices advisory board to define the safety for breast tissue expanders and medical devices in an MR environment. These mandatory medical device reports help establish safe patient care and assess patient care risks.

The FDA tests and labels medical devices to address hazards in the MR environment. The MR safety of manufacturers' tissue expanders is defined according to the FDA guidelines and regulations as MR Conditional or MR Unsafe. An MR Safe label is “a medical device that poses no known hazards resulting from exposure to any MR environment. MR Safe medical devices are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic” (FDA, 2023h, p. 3). There are currently no breast tissue expanders that are defined as MR Safe. An MR Conditional label is “a medical device with demonstrated safety in the MR environment within defined conditions, including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields” (FDA, 2023h, p. 3). An MR Unsafe label indicates “a medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment” (FDA, 2023h, p. 3).

By 2022, forty-two tissue expanders were cleared by FDA 510(k) in the United States, all labeled as MR Unsafe (FDA, General, and Plastic Surgery Devices Panel, 2022a; 2022b). In 2023, the FDA granted 510(k) clearance for the first tissue expander with an MR Conditional label with a non-magnetic port, marking a transformative step in breast cancer reconstruction. This advancement offers safer MRI solutions that improve health outcomes through earlier

detection of recurrent cancer (Establishment Labs, 2023).

Misinformation about MR safety has hindered cancer survivors with MR Unsafe labeled tissue expanders from undergoing MR examinations, increasing preventable cancer morbidity and mortality (Dibbs et al., 2019). The absence of MR Conditional tissue expanders available in the United States before 2023, combined with misinformation about MR safety, hindered the early detection of recurrent cancer, increasing preventable morbidity and mortality rates among high-risk breast cancer patients. Addressing these barriers necessitates adopting MR Conditional labeled tissue expanders with non-magnetic ports for post-cancer reconstruction. Trained MR radiologists may be unaware of MR safety guidelines they can follow when the benefits of MRIs outweigh the risks for patients with MR Unsafe labeled breast tissue expanders (Dibbs et al., 2019). Tissue expanders with a magnetic port impede early detection of recurrent cancer until they are surgically removed, according to the FDA and medical device guidelines.

Recognizing the need for MR Conditional labeled tissue expanders in the United States to mitigate MR Unsafe risks, a global medical technology company in California sought to identify and innovate a safer option already established as a standard of care in Spain (Establishment Labs, 2023; Merson et al., 2020). In Madrid, Spain, an MR Conditional labeled tissue expander with a non-magnetic (RFID-enabled) port was used in over 180 cases in a study involving 3-Tesla MR examinations, maintaining high imaging quality with no MRI-related patient injuries or complications (Establishment Labs, 2023).

Importance of Research

This research addresses the inability of high-risk breast cancer patients to have MR examinations without potential risks with an MR Unsafe labeled tissue expander. This highlighted the necessity for the FDA to grant clearance for the adoption of MR Conditional

labeled tissue expanders for use in the first stage of breast reconstruction for post-cancer patients in the United States. The FDA and the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee have classified tissue expanders and discussed associated risks, recommending limited surgical implantation of tissue expanders for no more than six months (FDA/General and Plastic Surgery Devices Panel, 2022a & 2022b). Patients with these tissue expanders face secondary risks with surgical placement, such as infection risks, complications from prolonged tissue expander implantation, and delayed or missed cancer diagnosis.

The common use of MR Unsafe labeled tissue expanders with magnetic ports in the first stage of breast reconstruction surgery poses significant barriers to MR examinations, which are crucial for the early detection of recurrent cancer in high-risk patients. MRIs for follow-up imaging examinations are labeled MR Unsafe, creating significant barriers to MRI access. According to the FDA, surgical medical equipment that is MR Unsafe restricts patients from MR examinations until the breast tissue expanders are surgically removed, impeding MR examination for early detection of recurrent cancer in high-risk patients (FDA, General and Plastic Surgery Devices Panel, 2022b).

Chapter 3: Methods

Study Design

This chapter outlines the methods used to review breast tissue expanders safe for MR examinations in the United States, focusing on MR Conditional and MR Unsafe labeled tissue expanders, their associated MRI risks, and the general benefits and risks of tissue expanders. Key elements include FDA safety guidelines, MDRs, and adverse events or complications related to MR Unsafe labeled tissue expanders. The goal is to collect data from research studies and interviews, identify breast tissue expanders that are safe for MR examinations, synthesize

findings, build a comprehensive understanding of the benefits and risks of MR Unsafe labeled tissue expanders, MR Conditional FDA-labeled tissue expanders, and their potential to reduce preventable breast cancer mortality. The scoping review identifies the steps to implement an MR Conditional labeled tissue expander for use in hospital settings in 2023.

The goal was to collect data from research studies and identify a breast tissue expander that allows safe MR examinations for patients with tissue expanders and synthesize findings in addition to supportive research on COVID-19 impact on breast reconstruction, FDA guidelines, FDA clearance on MR Conditional labeled tissue expanders, MR Unsafe labeled tissue expanders, early detection of recurrent breast cancer, breast tumor growth rates, tissue expander medical devices and a tissue expander informational packet.

Search Strategy and Eligibility

I systematically searched within the full text of the literature that included the search terms ‘Tissue Expander’ AND ‘MRI’ OR ‘FDA guidelines’ AND ‘MR safety’ OR ‘FDA guidelines’ AND ‘tissue expanders’ OR ‘COVID-19’ AND ‘breast cancer.’ The search aimed to gather data on safe MR examinations for post-cancer patients with tissue expanders with a magnetic port or a non-magnetic port utilized in the first stage of breast reconstruction. The inclusion criteria included evidence-based studies and reports focusing on breast cancer, reconstruction surgery, MR safety, MR screening, FDA classifications, and FDA guidelines. The studies were published between 2019 and 2024 and were primarily related to studies within the United States population. The exclusion criteria included studies unrelated to these topics or lacking credible data.

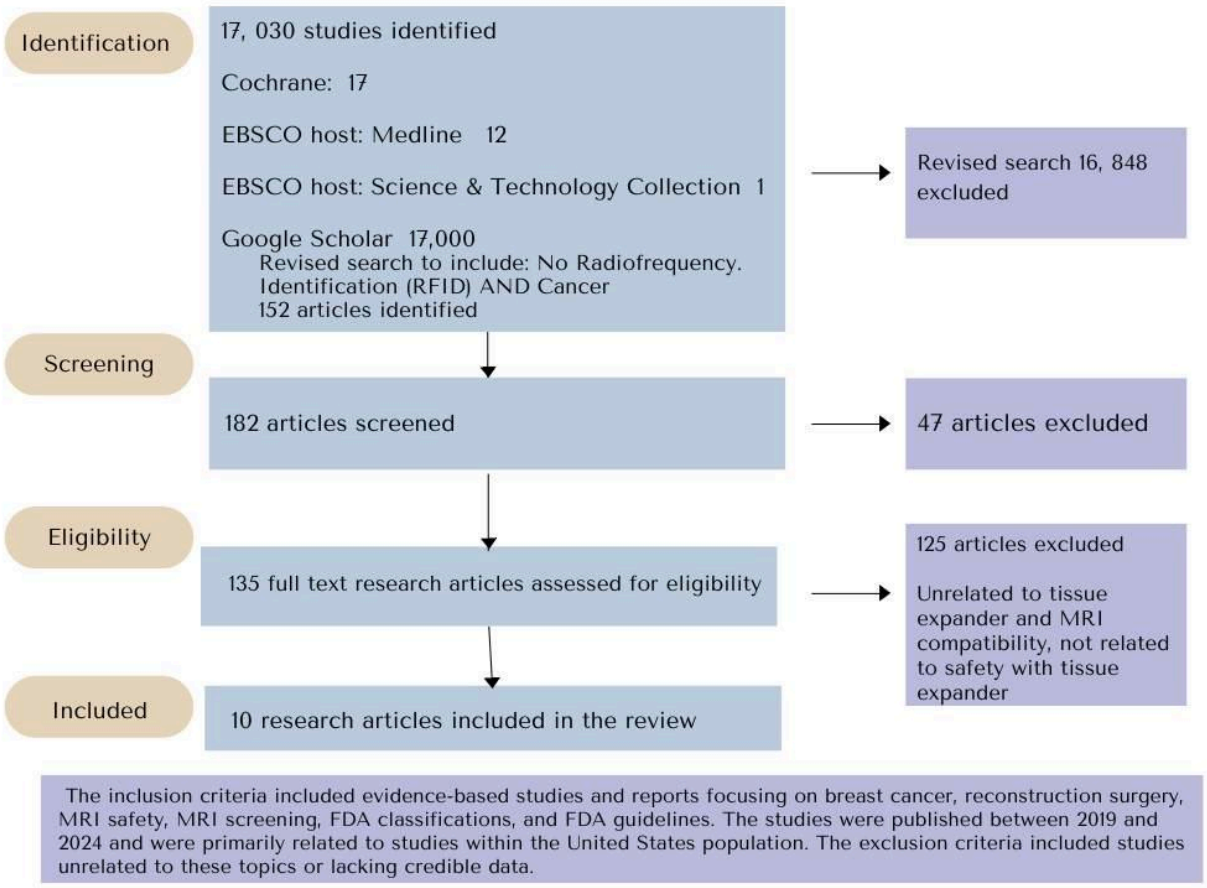
The eligible population included individuals who have undergone a mastectomy in the past twelve months due to breast cancer, requiring at least one tissue expander in the first

stage of breast reconstruction surgery. The intervention identifies a tissue expander that ensures safe MR examinations after surgical placement of at least one tissue expander in the first stage of breast reconstruction for post-operative evaluation, monitoring, earlier detection of recurrent cancer, and reducing preventable morbidity and mortality. Then, I compared the two different FDA medical device MR safety labels, MR Conditional and MR Unsafe. I gathered data from research studies and interviewed MR safety specialists and experts regarding MR safety. Then, I determined what identifies a tissue expander for safe MR examinations amongst the two different FDA medical device MR safety labels, MR Conditional and MR Unsafe. This outcome included FDA regulatory considerations, a literature review, identifying MR safety challenges with medical devices, and consulting with MRI experts and stakeholders.

Selection Process

The scoping review involved a comprehensive literature review search covering evidence-based published articles on Medline, Science & Technology Collection, Google Scholar, and Cochrane (Figure 2). The article search included tissue expander AND MRI (Tx All text) to find all my search terms and included articles published from 2019 to 2024. Articles were initially reviewed to reflect whether the topic was related to safe MR examinations, tissue expanders, and cancer. Articles that did not fit those guidelines were excluded. The search initially resulted in 135 full-text research articles being reviewed in detail, and ten articles directly related to safe MR examinations and tissue expanders were selected for inclusion.

Figure 2



Database Collection and Analysis

This search was aimed to gather data from research studies to identify breast tissue expanders that are safe for high-risk breast cancer survivors and ensure safe MR examinations after a breast tissue expander is surgically placed in the first stage of reconstructive surgery. The scoping review included MR safety guidelines for medical equipment surgically implanted in patients labeled as MR Conditional or MR Unsafe. The final selection of the scoping review included ten full-text articles in English articles published between 2019 and 2024.

Application of Public Health Competencies

IRB review or approval is not required for this research.

Master's in Public Health Foundational competencies

This scoping review study satisfies the foundational competency under planning and management (MPHF9) by promoting health through the design of a population-based policy, program, project, or intervention. The capstone scope review improves population health with the introduction of an MR Conditional labeled tissue expander in the United States.

Master's in Public Health Health Promotion Concentration competencies

Systemic thinking (MPHF22) foundational competency is demonstrated through the systems thinking tools to a public health issue. Systems thinking is applied in identifying the barriers and obstacles related to misinformation about the safety guidelines established for trained MR radiologists to follow for patients with breast tissue expanders that have magnetic ports when the patient's benefits of MR examination outweigh the MR examination risks with the patient having a magnetic port, as part of the tissue expander (Dibbs et al., 2019). This scoping review study satisfies the public health foundational competency focusing on policy in public health (MPHF13). This competency includes proposing strategies to identify stakeholders and build coalitions and partnerships that influence MR safety for high-risk cancer survivors with breast tissue expanders. The FDA clearance of the first MR Conditional labeled tissue expander with a non-magnetic port. The non-magnetic port is the critical factor in this context.

The health promotion concentration competency (HPROMPH2) involves analyzing and addressing contexts and key factors relevant to implementing evidence-informed health promotion strategies for high-risk cancer survivors with breast tissue expanders. This competency overlaps with HPROMPH3, which involves developing rigorous projects to improve public health outcomes and community well-being and reduce health disparities. Both competencies focus on the implementation of breast tissue expanders with a non-magnetic port that is labeled MR Conditional, allowing safe MR examination for early detection of recurrent

breast cancer and reducing preventable breast cancer mortality in high-risk cancer survivors.

Quality assessment

Quality assessment will be conducted to ensure the validity and reliability of the data. This involves evaluating the sources' credibility and the consistency of the findings. High-quality, credible data will be applied as the basis of the scoping review and findings. I have consulted with credible stakeholders in their specialty areas.

Chapter 4: Results

Description of Studies and Interviews

The scoping review of ten articles examined the types of tissue expanders used in breast reconstruction surgery in the U.S., specifically focusing on breast tissue expanders labeled MR Conditional and MR Unsafe. This review addressed the associated MR examination risks secondary to tissue expanders and general FDA information on tissue expanders and tissue expander risks. Findings were synthesized and categorized to identify differences and provide a comprehensive understanding of MR Unsafe FDA-labeled breast tissue expanders with magnetic ports and MR Conditional FDA-labeled breast tissue expanders with non-magnetic ports for breast cancer survivors undergoing reconstructive surgery following a mastectomy. Table 1 below categorizes the ten articles by findings and specifics if a patient with an MR Unsafe tissue expander with a magnetic port can undergo an MR examination with guidelines followed.

Table 1

Source	Findings	Can patients with an MR Unsafe tissue expander with a magnetic port undergo an MR examination with MR safety guidelines followed?
Dibbs et al. (2019)	The MR Unsafe labeling of tissue expanders should be reconsidered, as special precautions can mitigate risk. Research indicates minimal heating and minor magnetic field interactions. The metallic component in tissue expanders are insulated, reducing heating concerns. Trained MR radiologists can override MR Unsafe labels by assessing risks versus benefits for each individual case and implementing precautions such as using MRI scanners with a field strength not exceeding 1.5 Tesla, stabilizing the tissue expander, placing patients in a prone position to assist in stabilizing the tissue and continuously monitoring the patient during the MRI.	**Yes,** Trained MR radiologists can follow specific guidelines for MR examinations after a careful risk versus benefit assessment for each individual case.
Bayasgalan et al. (2020)	Tissue expanders with a magnetic port are classified as MR Unsafe, restricting patients from the diagnostic procedure. Case reports have noted issues like magnetic polarity reversal, infusion port dislodgement, and unsubstantiated burning sensations. While MRI under minimal conditions is possible, few facilities are willing to perform MRI scans on patients with breast tissue expanders that have a magnetic port due to safety concerns.	**No**, the tissue expander was classified as MR Unsafe. MR examinations are considered contraindications for patients with MR Unsafe tissue expanders with a magnetic port.
Christensen et al. (2022)	The packaging inserts for breast tissue expanders state that MRI is contraindicated for these devices. According to the U.S. Food and Drug Administration, MRI can cause complications for implanted breast tissue expanders with a magnetic port, including device malposition due to strong static magnetic fields and thermal injury from radiofrequency energy and magnetic fields. This is particularly concerning for patients who have undergone radiation therapy, as they are at a higher risk of injury and may require MRI for recurrent or metastatic disease. In the study, 12.5% of patients with these MR Unsafe expanders experience complications, with the most common issues being pain, discomfort, or burning (46.2%), expander or port displacement (38.5%), and MR signal loss (23.1%).	**Yes,** the authors recommend proceeding with caution and assessing the risk-to-benefit ratio for each patient. They suggest precautions such as prone positioning, reducing the MRI field strength, and stabilizing the tissue expander magnetic port. However, the appropriateness of MRI in these cases still needs to be determined due to the current medicolegal environment.

Source	**Findings**	**Can patients with an MR Unsafe tissue expander with a magnetic port undergo an MR examination with MR safety guidelines followed?**
Nahabedian & Hammer, (2022)	Manufacturers label tissue expanders as contraindicated for MRI due to risks like device displacement and imaging artifacts. No consensus guidelines exist for MRI use, and patience with tissue expanders is needed. Preparations such as prone positioning, reducing MRI field strength, and stabilizing the magnetic port are suggested. Surveys show mixed opinions among plastic surgeons on MR safety, with many recommending caution or removing the expander before an MR examination. Common complications include pain, expander displacement, and imaging artifacts. MRI should only be considered when benefits outweigh risks, based on individual patient assessments.	**Yes**, for the patient with an MR Unsafe tissue expander, an MR examination Should only be considered when the benefits outweigh the risks, based on individual patient assessments.
Noreña-Rengifo et al. (2022)	MRI unsafe breast tissue expanders with a magnetic port are generally considered a contraindication for MR examinations due to the risks of overheating, expander displacement, and artifacts.	**No**, MR examinations for patients with an MR Unsafe tissue expander are considered contraindications.
Clausen-Oreamuno et al. (2023)	Tissue expanders with magnetic ports are classified as MR Unsafe. MR Unsafe versus MR Conditional should be considered when choosing the appropriate tissue expander for a patient. Despite their contraindication, MRIs may be performed based on an individual risk versus benefit assessment, although severe artifacts can impair the image quality. Specific guidelines can be followed that can allow for limited and safe MR examinations. A new tissue expander with a non-magnetic port labeled MR Conditional is crucial for reducing risk and improving image quality during breast reconstruction. This highlights the importance of adopting MR Conditional labeled tissue expanders for surgical use, with MR examinations performed safely.	**Yes,** Although tissue expanders with a magnetic port present in patients are MR Unsafe, "reports have indicated that by following specific guidelines, certain MR examinations, albeit limited, may be performed safely" (p. 57).
Kanavou et al. (2023).	Breast tissue expanders with Magnetic elements in their filling ports are typically MR Unsafe. MR Conditional tissue expanders are compatible with MRI.	**No,** Tissue expanders with a magnet near the filling port are MR Unsafe
Park et al. (2023)	MRI poses thermal Risk due to high levels of electromagnetic fields, particularly for patients with breast tissue expanders with a magnetic port. These devices can accumulate electromagnetic fields in the tissues surrounding the tissue expanders, increasing the risk of thermal injury.	**No,** MRI scanning patients with implantable medical devices (e.g., a breast tissue expander with a magnetic port) can pose thermal risks in body regions surrounding the implants.

Source	Findings	Can patients with an MR Unsafe tissue expander with a magnetic port undergo an MR examination with MR safety guidelines followed?
Schiaffino et al., (2023)	MR examinations are contraindicated for patients with MR Unsafe breast tissue expanders due to risks of complications such as pain, displacement of the magnetic port, and extensive image artifacts that impede MRI interpretation. Although some studies suggest that MR examinations might be performed under selected conditions, magnetic components in these tissue expanders pose a significant risk, and MR examination is contraindicated. An alternative is using MR Conditional tissue expanders with a non-magnetic port, which allows for safe imaging.	**No**, MR examination for patients with an MR Unsafe tissue expander is contraindicated and can lead to injury. Safer alternatives include MR Conditional tissue expanders with non-magnetic ports.
Schoberleitner et al. (2023)	Breast tissue expanders with magnetic ports are considered MR Unsafe. Tissue expanders with a non-magnetic port and radio frequency identification (RFID) devices can safely undergo MR examinations.	**No,** Breast expanders with magnetic ports are unsafe for MR examinations. Patients with MR Conditional tissue with a non-magnetic port can have an MR examination.

Summary of Findings

The scoping review involved ten evidence-based research articles examining the necessary steps to identify safe breast tissue expanders for high-risk breast cancer survivors, particularly those utilized in the first stage of reconstructive surgery. This ensures safe MR examinations for early detection of recurrent cancer post-operative evaluation and monitoring, thereby reducing preventable breast cancer morbidity and mortality. The scoping review studied included individuals who underwent a mastectomy in the past 12 months due to breast cancer and required either an MR Unsafe labeled tissue expander with a magnetic board or an MR Conditional labeled breast tissue expander for the first stage of breast reconstruction surgery.

FDA and medical device guidelines state that MR Unsafe devices pose unacceptable medical risks for patients in an MR environment, creating barriers for cancer survivors needing

MR examinations (FDA, 2023b). MR screening is the gold standard for early detection of recurrent cancer in high-risk patients (Dahan et al., 2021). Until October 2023, MR Conditional FDA-labeled tissue expanders were inaccessible in the United States. The COVID-19 pandemic delayed the early detection of recurrent cancer, as elective surgeries were initially stopped with precedence in hospital care focused on COVID-19 patients, and office visits for oncology patients were limited. Breast reconstruction surgeries were halted except for those patients with more aggressive cancer, such as HER2-positive or triple-negative breast cancer (Uscher et al., 2023). With the highest incidence of recurrent cancer in the first twelve months post-cancer, high-risk post-cancer survivors must have access to safe MR examinations. A systematic review revealed that the average duration for a breast cancer tumor to double in size is 180 days, highlighting the need for safe MR examinations (Dahan et al., 2021)

Trained MR radiologists have guidelines for MR Unsafe labeled tissue expanders with a magnetic port. These include MR settings and patient MR examination guidelines to avoid magnetically induced displacement force, magnetically induced torque, and radio frequency (RF) induced heating by specific settings for the maximum spatial field gradient, RF excitation, any RF transmit coil restrictions, operating mode settings, specific absorbance rate (SAR) for maximum whole body imaging, SAR for maximum head imaging and the total scan duration (FDA, 2023h, pp. 25-26). Established MR procedural guidelines advise trained MR radiologists on various MRI settings they can follow when the benefits of an MR examination outweigh the risks for patients with an MR Unsafe breast tissue expander with a magnetic port (Dibbs et al. , 2019).

The FDA and medical device guidelines state that MR Unsafe devices pose unacceptable medical risks for patients to be in an MR environment, creating barriers for cancer survivors

needing access to MR imaging (FDA, 2023b). MR safety specialists described specific settings in which the MRI benefits for the patient outweigh the risks. Trained MR radiologists can apply these settings, but not all trained MR radiologists may be familiar with these guidelines, and there are potential patient risks for patients with an MR Unsafe labeled tissue expander. Although there are systematic reviews, assessing the potential direct association of patient symptoms with at least one tissue expander with a magnetic part to the patient outcomes requires a deeper level of data and is limited by the Health Insurance Portability and Accountability Act.

Christensen et al. (2022) noted, “The authors report that 12.5% of patients experienced complications. Most frequent among these was pain, discomfort, or burning in 46.2%; expander or port displacement in 38.5%; and magnetic resonance signal loss in 23.1%” (pp. 969–970). The current incidence of complications in 12.5 % of patients with a tissue expander with a magnetic port is significant (Christensen et al., 2022). I consulted with the FDA Center for Biological Evaluation and Research department and one that co-authored a few articles related to RF safety with implantable medical devices coupling with 3.0 Tesla (T) MRI. I clarified the potential barrier to labeling breast tissue expanders MR Conditional with all breast tissue expanders with magnetic ports labeled MR Unsafe. The response reflected that the heat generated from the interaction of the MR generated electric fields and the medical device causes safety concerns. The heat can injure the patient directly or cause damage to the device. MR safety specialists described specific settings established when the MRI benefits for the patient outweigh the risks. Trained MR radiologists can apply these settings, but there are still potential risks.

Specific MR safety guidelines exist for trained MR radiologists to follow when conducting MR examinations on patients with MR Unsafe tissue expanders, provided the benefits outweigh the risks (Dibbs et al., 2019). Dibbs et al. (2019), Christensen et al. (2022),

Nahabedian & Hammer (2022), and Clausen-Oreamuno et al. (2023) all noted that patients with a tissue expander with a magnetic port can undergo an MR examination with caution after conducting a careful risk-versus-benefit assessment for each individual case. Dibbs et al. (2019) and Clausen-Oreamuno et al. (2023) noted that by following specific guidelines, MR examinations may be performed safely for patients who present with MR Unsafe labeled tissue expanders that contain a magnetic port.

FDA, General and Plastic Surgery Devices Panel (2022a, 2022b) highlights the barriers and risks associated with MR Unsafe labeled tissue expanders. Bayasgalan et al. (2020), Christensen et al. (2022), Nahabedian & Hammer (2022), Noreña-Rengifo et al. (2022), Schiaffino et al. (2023), Park et al. (2023) and Schiaffino et al., (2023) noted that off-label use of MR examinations can pose risks and lead to injury or pain or have listed reported injuries for patients and extensive image artifacts for patients that have an MR Unsafe labeled TE with a magnetic port. Bayasgalan et al. (2020), Noreña-Rengifo et al. (2022), Kanavou et al. (2023), Park et al. (2023), Schiaffine et al. (2023), and Schoberleitner et al. (2023) and FDA General and Plastic Surgery Devices Panel (2022a, 2022b), stated no MR examinations should be completed for patients with breast tissue expanders labeled MR Unsafe with magnetic ports. These breast tissue expanders with a magnetic port can delay the early detection of recurrent cancer. MR examinations are limited until the tissue expanders are surgically removed per the FDA, General and Plastic Surgery Devices Panel (2022a, 2022b).

By 2022, forty-two tissue expanders were cleared by FDA 510(k) in the United States, and all were labeled as MR Unsafe (FDA, General, and Plastic Surgery Devices Panel, 2022a; 2022b). In 2023, the FDA granted 510(k) clearance for the first tissue expander with an MR Conditional non-magnetic port, marking a transformative step in breast cancer reconstruction.

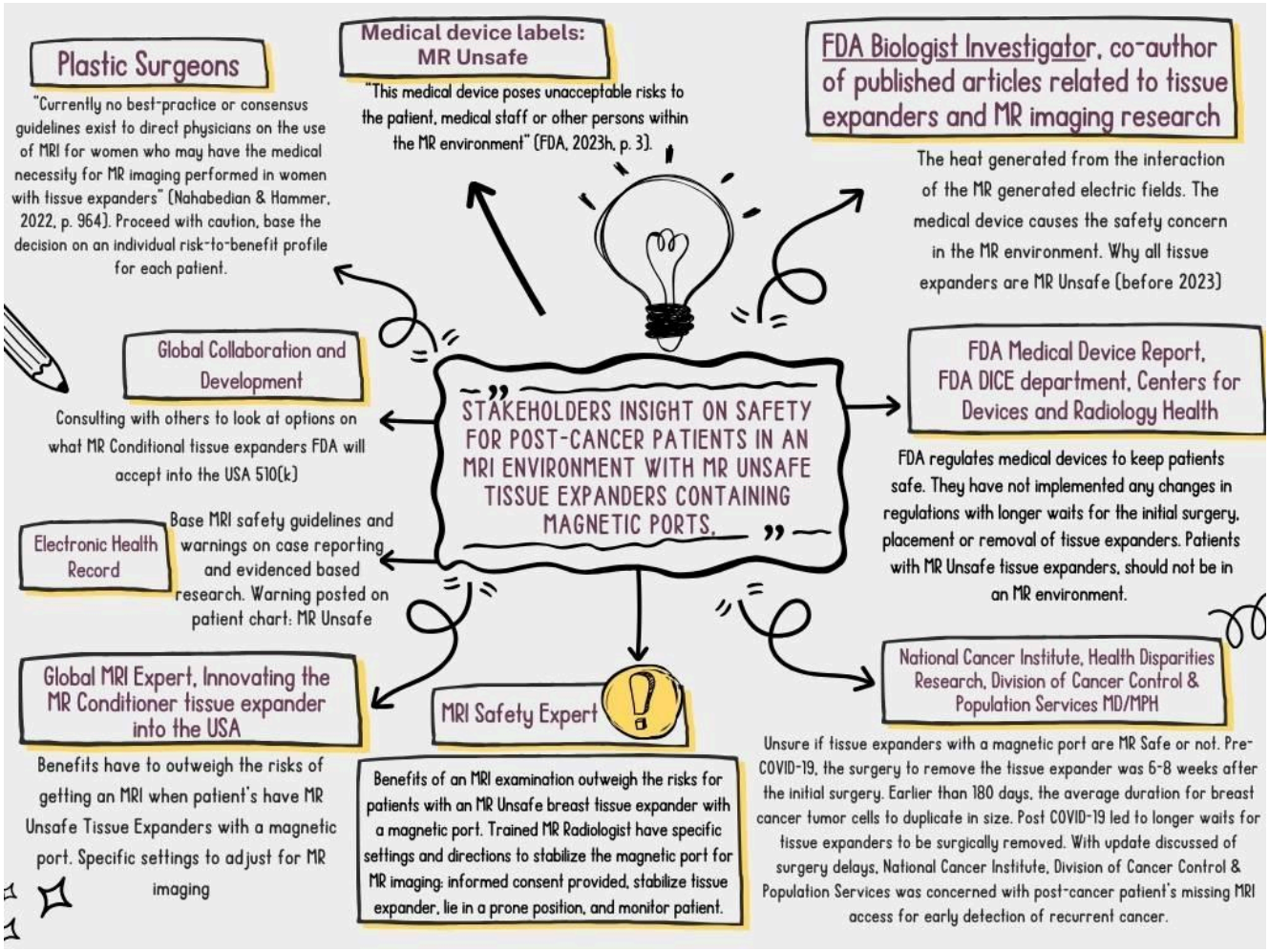
This advancement offers safer MRI solutions that improve health outcomes through earlier detection of recurrent cancer (Establishment Labs, 2023). An MR Conditional medical device has "demonstrated safety in the MR environment within defined conditions, including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields" (FDA, 2023h, p. 3). Early cancer detection with MR examinations is crucial for patients who are at a high risk for recurrent cancer, and allowing safe MR examinations address these patient needs.

The introduction of MR Conditional labeled tissue expanders with non-magnetic ports, as detailed by Establishment Labs (2023), represents a significant advancement. Merson et al. (2020) in Madrid reported the successful use of an MR Conditional tissue expander with a non-magnetic port, high imaging quality, and no MR-related complications. Clausen-Oreamuno et al. (2023), Kanavou et al. (2023), Schiaffino et al. (2023), and Schoberleitner et al. (2023) stated that patients with a tissue expander that has a non-magnetic port with a radio frequency identification device, avoid risks to patients and image quality disturbances with an MR examination. These MR Conditional tissue expanders enable safe MR examinations, which are crucial for the early detection of recurrent cancer in high-risk patients.

Stakeholders were identified and engaged in discussions to gain insights into MR Unsafe, or MR Conditional FDA labeled tissue expanders. MRI experts played a crucial role in promoting the adoption of MR Conditional tissue expanders in the United States in 2023. I interviewed stakeholders that including the following: an FDA Biologist Investigator, co-author of a few published articles reviewed related to tissue expanders and MR imaging research; FDA DICE department; a Physician/MPH with the National Cancer Institute, Health Disparities Research, Division of Cancer Control & Population Services; MR safety expert, Global MRI

expert who innovated the MR Conditional tissue expander into the USA; Global MR PhD Collaborations and Development with a Medical Device Company; Electronic Health Record Systems Representative, Plastic Surgeons; University Professor of Radiology, Physics, and Biomedical Engineering; Oncologist, and an Oncology Imaging Specialist. The stakeholders' responses were similar to the published articles reviewed, reflecting whether a patient with an MR Unsafe tissue expander with a magnetic port can have MR examinations with MR safety guidelines followed. The various findings in the stakeholders' interviews were similar to those found in the literature reviewed. A summary of the various findings are discussed below.

Figure 2



Chapter 5: Discussion

Health Belief Model

This Health Belief Model (HBM) is a public health theory that illustrates the necessity for change due to risks or limitations in surgical medical equipment that restricts imaging, such as MR Unsafe tissue expanders. This HBM illustrates the public health implications and the need for change by addressing key components.

Figure 3

Concept	Concept Definition	Application to MR Unsafe Tissue Expanders	Application to MR Conditional Tissue Expanders	Intervention Strategy to Influence Concept
Perceived Susceptibility	Belief about the chances of getting a condition or a disease.	Patients may fear that any reconstructive surgery that includes surgical placement of a tissue expander or a permanent implant following a mastectomy may obscure the ease of detecting recurrent cancer, leading them to not elect any further reconstructive surgeries (FDA, General, and Plastic Surgery Devices Panel, 2022b).	Patients may feel less susceptible to complications if they know the tissue expander is an MR Conditional tissue expander with a non-magnetic port, reducing restrictions and risks when undergoing an MRI.	Provide education on the safety and risk factors associated with MR Unsafe and MR Conditional tissue expanders, emphasizing the advanced safety features of MR Conditional tissue expanders with a non-magnetic port.
Perceived Severity	Belief about the severity of contracting a disease or condition, including consequences of risks and conditions.	Patients might perceive a higher severity of potential complications due to the inability to use MRI for detecting medical issues or recurrent cancer.	Patients might perceive a lower severity of potential complications because MR Conditional tissue expanders with a non-magnetic port allow for easier, safer, and more accurate monitoring and detection of medical issues or recurrent cancer.	Highlight the medical benefits and reduced risk of severe complications using MR Conditional tissue expanders with a non-magnetic port. Allows the patient to undergo necessary MRI scans safely.

Concept	Concept Definition	Application to MR Unsafe Tissue Expanders	Application to MR Conditional Tissue Expanders	Intervention Strategy to Influence Concept
Perceived Threat	Construct formed with the combination of susceptibility and severity.	The perceived threat may be due to both the fear of undetected complications and the high severity of potential outcomes if complications are not monitored with MRI, which is the best radiological modality for high-risk recurrent cancer.	The perceived threat may be lower as MR Conditional tissue expanders with a non-magnetic port reduce the fear of undetected complications and allow for the best radiological modality in MR screening for high-risk recurrent cancer.	Develop information campaigns and support groups to address fears and provide comprehensive information about the lower risks associated with MR Conditional tissue expanders with a non-magnetic port, aiming to reduce the overall perceived threat.
Perceived Benefits	Beliefs of positive features of adopting a healthy behavior.	Patients may perceive fewer benefits due to restrictions on MRI usage, leading to concerns about the effectiveness of monitoring and early detection of recurrent cancer.	Patients may perceive significant benefits, including ease of monitoring for recurrent cancer, early detection of complications and cancer, and overall improved safety, leading to a higher likelihood of opting for reconstructive surgery.	In patient education materials, emphasize the benefits of MR Conditional tissue expanders with a non-magnetic port, focusing on improved health outcomes and decreased stress due to easier and safer monitoring capabilities, applying the best radiological modality, and monitoring for recurrent cancer.
Perceived Barriers	Beliefs about obstacles to performing a behavior and the negative aspects of adopting a healthy behavior.	High perceived barriers due to MRI restrictions, MR Unsafe tissue expander with a magnetic port, potential need for alternative imaging methods, and increased anxiety about undetected complications.	Lower perceived barriers, such as MR Conditional tissue expanders with a non-magnetic port, reduce the need for alternative imaging methods and alleviate concerns about undetected complications, making the process smoother and less stressful.	It offers resources to identify and reduce misperceptions and barriers, such as information on reduced restrictions and increased convenience or MR Conditional tissue expanders with a non-magnetic port, and it provides support to help patients navigate their reconstructive surgery options.

Concept	Concept Definition	Application to MR Unsafe Tissue Expanders	Application to MR Conditional Tissue Expanders	Intervention Strategy to Influence Concept
Cues to Action	Internal or external factors that can trigger the health behavior.	Fear of undetected complications and advice from healthcare providers can act as cues to avoid MR Unsafe tissue expanders with a magnetic port and consider alternative options.	Recommendations from healthcare providers and information on the benefits and safety of MR Conditional tissue expanders with a non-magnetic port can act as strong cues to choose these tissue expanders.	Create clear and compelling communication to promote awareness and strategies, including testimonials, provider recommendations, and success stories to serve as cues to action, encouraging patients to consider MR Conditional tissue expanders with a non-magnetic port.
Self-Efficacy	Beliefs that one can perform the recommended health behavior (confidence)	Patients may feel less confident managing their health if they perceive high risks and barriers associated with MR Unsafe tissue expanders with a magnetic port, potentially leading to the avoidance of reconstructive surgery.	Patients may feel more confident in managing their health and undergoing reconstructive surgery if they perceive MR Conditional tissue expanders with a non-magnetic port as safe and manageable, boosting their self-efficacy.	Increase patient self-efficacy through education, reassurance, and clear guidance on the safety and advantages of MR Conditional tissue expanders with a non-magnetic port. This includes training on self-monitoring techniques and regular follow-up support from healthcare providers.

Note. This table integrates the Health Belief Model concepts with specific applications and intervention strategies related to MR Unsafe with a magnetic port and MR Conditional tissue expanders with a non-magnetic port, aiming to influence patients' perceptions and actions.

Adapted from “Chapter 5 Health Belief Model,” by Glanz et al., 2015, p. 76-80.

Public Health Implications

Despite these advancements in MR Conditional labeled tissue expanders available in the United States, gaps remain in implementation by plastic surgeons in a hospital setting, Collaborating with stakeholders to promote the safe use of these expanders by plastic surgeons in a hospital setting is crucial. Many plastic surgeons still use traditional tissue expanders with a magnetic port, making MR environments inaccessible and creating barriers for cancer survivors who need safe MR examinations for early detection of recurrent cancer. The existing literature may not fully address the barriers to the innovation of MR Conditional tissue expanders in hospital settings despite their availability in the United States since October 2023.

After implementing a new medical device, it is essential to identify gaps and collaborate with stakeholders to promote the safe use of MR Conditional labeled tissue expanders in a hospital setting. Promoting the adoption of MR Conditional labeled tissue expanders across hospitals in the United States is necessary for improving patient outcomes by providing a safer option for breast reconstruction surgery.

Ensuring the widespread adoption of MR Conditional tissue expanders is vital to enhancing patient safety and improving health outcomes. The innovation of MR Conditional tissue expanders in the United States can significantly reduce the risks associated with MR examinations for patients with traditional expanders, thus promoting early cancer detection and providing a safer option for breast reconstruction surgery. Public health initiatives can focus on educating healthcare providers and patients about the benefits of MR Conditional tissue expanders and advocating for policy changes to support their implementation.

Limitations

The scoping review aims to address the gaps by applying the Health Belief Model to understand the factors influencing the adoption process of MR Conditional tissue expanders. The MR Conditional breast tissue expander innovation can provide insight into potential barriers to implementing a surgical medical device in a hospital setting. Existing literature may need to fully address the depth of involvement of all government, regulatory, and independent agencies in an innovation. Multiple entities, from the FDA to hospitals, could be involved in implementing MR Conditional devices.

The various entities involved in an innovation, regulation, and implementation of a new medical device include: global research and consulting, global regulatory agencies, intellectual property and patent organizations, governmental and regulatory agencies, accreditation and standards organizations, professional societies and associations advocating for best practices, hospital and healthcare systems, plastic surgeons and healthcare providers, independent executive organizations or free-standing organizations, and research and academic institutions After implementing a new medical device, it is essential to identify gaps and collaborate with stakeholders to promote the safe use of MR Conditional tissue expanders in a hospital setting.

With all the organizations in innovation, electronic medical charting exemplifies the importance of taking a broad view of all the entities involved. This allows continuity in implementing a new medical device and avoids misinformation. I interviewed a prominent electronic medical record corporation in the United States to gain insight into whether electronic medical records implement any MR safety guidelines, specifically when a patient has a medical or surgical device. I was informed that if a patient has a medical or surgical MR Unsafe device, their electronic patient chart is flagged when they arrive for MR imaging to be completed. The patient's electronic medical system is flagged upon arrival for the MR examination if they have

at least one tissue expander, warning the MRI technician that the patient should not enter the MR environment due to the presence of an MR Unsafe medical device. This MR safety warning is to protect patients.

This electronic patient charting corporation stated that all tissue expanders are flagged as MR Unsafe and were unaware of the new MR Conditional tissue expander approved by the FDA in 2023. The MR Unsafe warning does not appear in the patient chart when an MRI is ordered or when the MR pre-screening questions are completed. The electronic medical charting corporation noted that they will consider implementing these changes when their system is updated. This reflects the importance of taking a broader look when there is an innovation. Here is a complete list of all organizations related to the innovation, regulation, and implementation of medical devices in the United States.

I. Global Regulatory Agencies: Ensure safety and efficacy through approved processes and guidelines
    A. International Organizations
        1. International Medical Device Regulators Forum (IMDRF)
        2. World Health Organization
        3. International Clinical Trials Registry Platform: To improve research
        4. transparency and strengthen the validity of evidence-based research, a complete view of research should be accessible to all healthcare decision-makers (World Health Organization, 2024).
    B. National Regulatory Agencies
    C. Spanish Ministry of Health, Social Services, and Equality
    D. Spain Agency of Medicines and Medical Devices (AEMPS)

II. Global Research and Consulting

III. Intellectual Property and Patent Organizations

IV. Governmental and Regulatory Agencies (United States)

A. Department of Health and Human Services (DHHS)

1. United States Food and Drug Administration (FDA)

a) Center for Devices and Radiological Health (CDRH)

(1) Office of Device Evaluation

(2) Office of Compliance

(3) Office of Surveillance and Biometrics

b) Center for Biologics Evaluation and Research (CBER)

2. National Institutes of Health

a) National Cancer Institute

(1) Division of Cancer Control and Population Sciences

(a) Health Disparities Research, Health Disparities and Health Equity

b) National Institute of Biomedical Imaging and Bioengineering (NIBIB)

3. Centers for Disease Control and Prevention (CDC)

a) Division of Cancer Prevention and Control

4. Agency of Healthcare Research and Quality (AHRQ)

5. Centers for Medicare & Medicaid Services (CMS)

V. Accreditation and Standards Organizations

A. American Society for Testing and Materials: determine safety

B. The Joint Commission (TJC)

C. International Organization for Standardization (ISO)

D. American College of Radiology (ACR)

VI. Professional Societies and Associations Advocating for best practices

A. Radiological Society of North America (RSNA)

B. American Society of Plastic Surgeons

C. International Society of Magnetic Resonance in Medicine

VII. Hospitals and Healthcare Systems

A. Individual Hospitals

1. Hospital Safety Committees
2. Risk Management
3. Radiological Departments
4. Surgical Departments
5. Plastic Surgery
6. MR Safety Officers
7. Infection Control Departments

VIII. Plastic Surgeons and Healthcare Providers

A. Individual Plastic Surgeons

IX. Independent executive organizations or Free-Standing Organizations

A. MR Safety and Guidelines Organizations

1. The Institute of Magnetic Resonance Safety, Education, and Research (IMRSER)
2. MR Safety Experts and Consultants

3. Clinical Guidelines and Protocols for MRI use in Patients, Surgical Implants of Medical Devices

B. Medical Device Companies

1. Company Innovating MR Conditional Tissue Expanders

a) Research and Developmental Departments

b) Regulatory Affairs Department

c) Clinical Trials Management

d) Safety and Compliance Teams

2. Focusing on Medical Device Research

C. Electronic Health Record System

X. Research and Academic Institution

A. Universities/Colleges

1. Medical Research

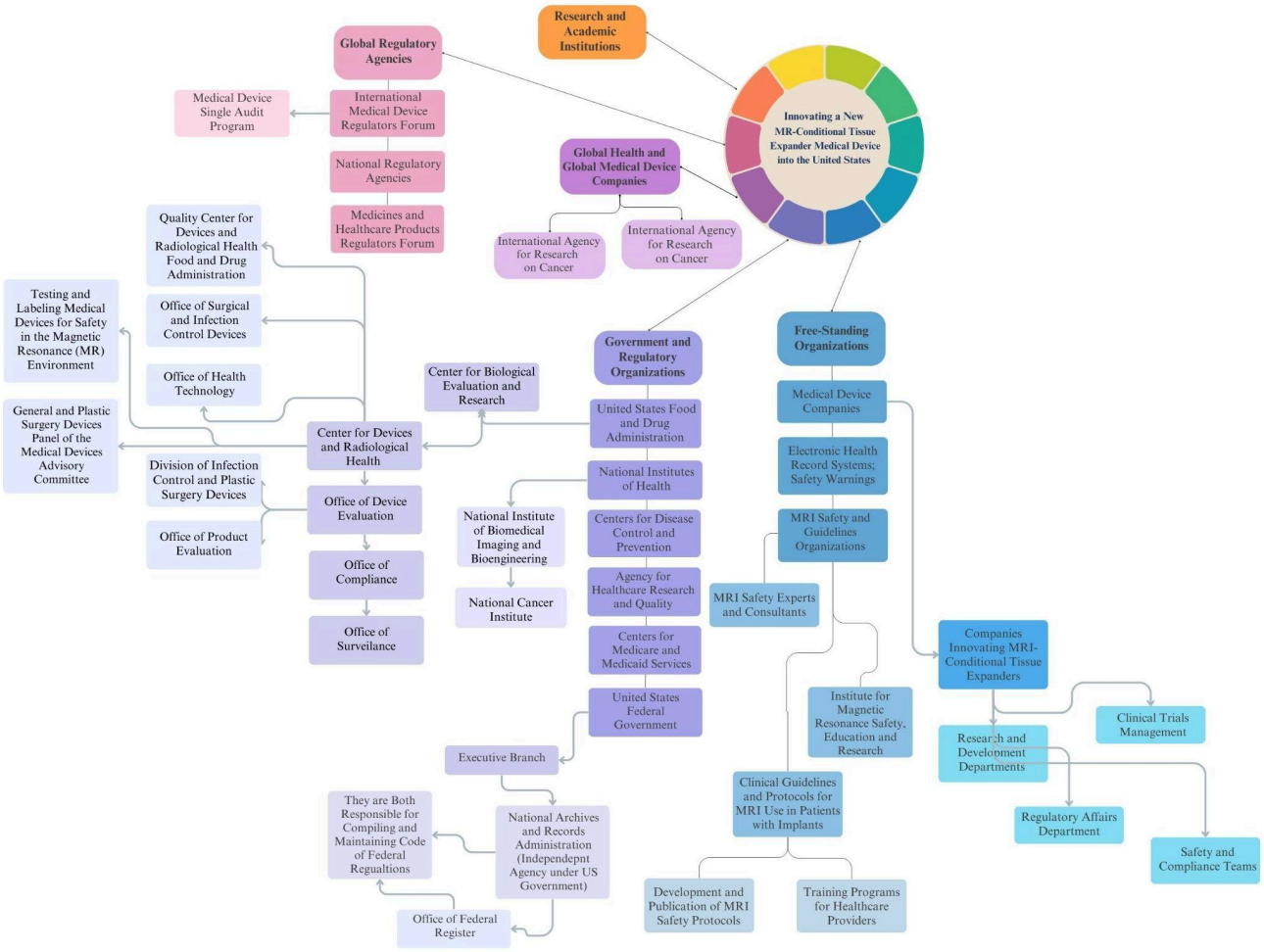
Summary

The analysis covered several key topics: FDA classification of tissue expanders, FDA, Medical Device Advisory Committee findings, MR imaging, breast tissue expanders, the impact of COVID-19 on breast reconstruction, expanders, and a broad view of entities involved in innovation and FDA clearance of MR Conditional tissue expanders. This scoping review applies the Health Belief Model to explain factors influencing the FDA to grant 510(k) clearance in 2023 for the first MR Conditional tissue expander with a non-magnetic port available in the United States (Establishment Labs, 2023). Post-510 (k) clearance ensures labeling and packaging compliance with FDA guidelines. Multiple organizations are involved in the innovation and implementation of MR safety guidelines, and hospitals have their policies, guidelines, risk

management, and education programs before implementing a new medical device. The scoping review and consultations with stakeholders emphasized the importance of safe MR examination guidelines for both MR Unsafe labeled tissue expanders and MR Conditional labeled tissue expanders. Ensuring safe MR examinations is crucial to mitigate risks for patient injury and enable early detection of recurrent cancer in high-risk breast cancer patients.

Figure 4

Governmental Bodies, Organizations and Agencies Involved in Research, Global Innovation and Consulting.



Note.These orgaizations collectively contribute to the innovation, regulatory approval, implementation and promotion of MR-conditional tissue expanders to improve patient outcomes and advance breast cancer care.

Figure 5

Governmental Bodies, Organizations and Agencies Involved in Research, Global Innovation and Consulting.

Note.These orgaizations collectively contribute to the innovation, regulatory approval, implementation and promotion of MR-conditional tissue expanders to improve patient outcomes and advance breast cancer care.

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